

Notice of Allowability

Application No. 09/890,973	Applicant(s) HYLANDS ET AL.	
Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. This communication is responsive to Interview of 04/30/04.
- 2. The allowed claim(s) is/are 1,2,4-6 and 8-16.
- 3. The drawings filed on 08 August 2001 are accepted by the Examiner.
- 4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 - 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
- 7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application (PTO-152)
- 6. Interview Summary (PTO-413), Paper No./Mail Date 04/30/04.
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

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DETAILED ACTION

1. Amendment and Response filed on 04/26/04 are acknowledged. Claims 1-16 are pending in the specification.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Arthur R. Crawford and Celia Keen on 04/30/04.

The application has been amended as follows:

Claim 1 (Amended): A process of establishing a standard specification for a medicinal plant material, the process comprising:

- (i) selecting a sample of the medicinal plant material, which sample is known to possess a particular desired property, as a standard sample;
- (~~ii~~) (ii) preparing a test solution or test extract of a said standard sample; ~~of the medicinal plant material which is known to possess the or each property required for the standard;~~
- (~~iii~~) (iii) submitting the said solution or extract to two or more analytical methods including (a) a combination of NMR spectroscopy and a computer-based pattern recognition technique, said combination comprising submitting the solution or extract to NMR spectroscopy, recording one or more NMR spectra and submitting data obtained from the or each NMR spectrum to a multivariate analysis, and (b) one or more biological profiling techniques which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis;

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- ~~(iii)~~ (iv) obtaining results from the analytical methods used in step ~~(ii)~~ (iii); and
~~(iv)~~ (v) defining a standard specification for the said plant material on the basis of
the results obtained in step ~~(iii)~~ (iv);

the process being conducted such that the NMR data submitted to the multivariate analysis reflect the totality of the compounds in the plant material which respond to the NMR technique being used.

Claim 2 (Twice Amended): A process of providing a desired sample of a medicinal plant material, which sample complies with a the standard specification for that material ~~which has been defined~~ by the process of claim 1, the process comprising:

- (i) preparing a test solution or test extract of a candidate sample of the medicinal plant material;
- (ii') submitting the said solution or extract to two or more analytical methods including (a) a combination of NMR spectroscopy and a computer-based pattern recognition technique, said combination comprising submitting the solution or extract to NMR spectroscopy, recording one or more NMR spectra and submitting data obtained from the or each NMR spectrum to a multivariate analysis, and (b) one or more biological profiling techniques which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis;
- (iii') obtaining results from the analysis of step (ii');
- (iv') selecting the candidate sample if the results in step (iii') comply with the standard specification for the said material established in step (iv) of the process defined in claim 1;

the process being conducted such that the NMR data submitted to the multivariate analysis reflect the totality of the compounds in the plant material which respond to the NMR technique being used.

Cancel claim 3.

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Claim 4 (Amended): A The process according to claim 1, which further comprises representing the results of wherein the combination of NMR spectroscopy and a computer-based pattern recognition technique comprises:

- (a) ~~submitting the test solution or test extract to NMR spectroscopy and recording one or more NMR spectra; and~~
- (b) ~~submitting the data obtained from the or each NMR spectrum to a~~ the multivariate analysis to generate as one or more points on a score plot.

In **claims 5-6 and 8** change [A] to The in front of "process".

Claim 9 (Amended): A process of establishing a standard specification for a medicinal plant material, the process comprising:

- (i'') selecting a sample of the medicinal plant material, which is known to possess a particular desired property, as a standard sample;
- (i''') (ii'') ~~preparing a test solution or test extract of a said standard sample; of the said plant material which is known to possess the or each property required for the standard;~~
- (ii''') (iii'') ~~submitting the test solution or test extract to NMR spectroscopy and recording one or more spectra;~~
- (iii''') (iv'') ~~submitting the data obtained from the or each said NMR spectrum, those data reflecting the totality of the compounds in the plant material which respond to the NMR technique being used, to a multivariate analysis to generate one or more points on a score plot; and~~
- (iv''') (v'') defining a sphere of acceptability around the points generated in step (iv'') as the, or as part of the, standard specification for the said plant material;

In **claim 10:** change [A] to -- The -- before "process" and change [(iii''')] to -- (iv'') --.

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Claim 11 (Amended): A process of providing a desired sample of a medicinal plant material, which sample complies with a the standard specification for that material ~~which has been~~ defined by the process of claim 9, the process comprising:

- (i^{'''}) (i^{'''}) preparing a test solution or test extract of a candidate sample of ~~the~~ said plant material;
- (ii^{'''}) (ii^{'''}) submitting the test solution or test extract to NMR spectroscopy and recording one or more spectra;
- (iii^{'''}) (iii^{'''}) submitting the data obtained from the or each said NMR spectrum, reflecting the totality of the compounds in the plant material which respond to the NMR technique being used, to a multivariate analysis to generate one or more points on a score plot; and
- (iv^{'''}) (iv^{'''}) selecting the candidate sample as said desired sample which complies with said standard specification only if the points generated on the score plot in step (iii^{'''}) fall within a the sphere of acceptability as defined ~~in the~~ standard specification established in step (iv^{'''}) (v^{'''}) of the process defined ~~in~~ of claim 9;

In claims 12-14 change [A] to -- The --.

Claim 15 (Amended) A The process according to claim 1 wherein the standard sample of ~~the medicinal plant material which possesses said the or each property desired for the standard is~~ a sample of authenticated or audited plant material of which the provenance is known.

Claim 16 (Amended): A process of establishing a standard specification for a medicinal plant material, the process comprising:

- (i) selecting a sample of the medicinal plant material, which sample is known to possess a particular desired property, as a standard sample;
- (i) (ii) preparing a test solution or test extract of a said standard sample; ~~of the medicinal plant material which is known to possess the or each property required for the standard;~~
- (ii) (iii) submitting ~~the~~ said solution or extract to two or more analytical methods

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including (a) a combination of NMR spectroscopy and a computer-based pattern recognition technique, said combination comprising submitting the solution or extract to NMR spectroscopy, recording one or more NMR spectra and submitting data obtained from the or each NMR spectrum to a multivariate analysis, and (b) one or more biological profiling techniques which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis, said proteomics analysis comprising

- (a') providing a target cell selected according to the clinical indication in which the medicinal plant is active and incubating the target cells with the test solution or test extract; and
- (b') subjecting the incubated cells to get electrophoresis on a 2-D gel and observing the change in protein expression in the calls as a result of exposure to the said solution or extract;

~~(iii)~~ (iv) obtaining results from the analytical methods used in step ~~(ii)~~ (iii); and
~~(iv)~~ (v) defining a standard specification for the said plant material on the basis of the results obtained in step ~~(iii)~~ (iv);

the process being conducted such that the NMR data submitted to the multivariate analysis reflect the totality of the compounds in the plant material which respond to the NMR technique being used.

The following is an examiner's statement of reasons for allowance: the examiner agrees with the applicants' arguments that the prior art does not teach a combination of NMR spectroscopy, multivariable analysis and proteomics for standardization of medicine plant materials. The applicants' arguments regarding enablement issues are also convincing, and the examiner's amendment clarifies the language of the claims.

Claims 1-2 and 4-6 and 8-16 are allowed. The new numbering of claims is 1 through 14.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
4/30/04

